REMARKS/ARGUMENTS

Claims 9-23 are active in this application. Claims 9 and 17 are amended to correct typographical errors which are apparent from the originally presented claims. No new matter or issues are raised by entering these amendments.

Applicants thank the Examiner for withdrawing most of the previous rejections except for the rejection based on the combination of Shastri (U.S. Patent Publication 2003/0078215) in view of RxList Monographs (2002). Notwithstanding the differences explained in the previous response, the rejection was maintained rejection because "it is the position of the Examiner that the bioactive agents of the prior art as recited are directed toward the broad disclosure of the activation. One of ordinary skill in the art of drug preparation would have the understanding of preparing that active agent with a salt, if the salt of the drug would better suit the preparation."(page 3 of the Official Action). However, this conclusion misses a fundamental point of difference, which is that the present invention is based on the discovery that certain agents can stabilize fosfomycin tromethamol (Claim 9 is directed to a method of stabilizing and Claim 17 is directed to a composition in which the agent is present in an amount effective for stabilizing). There is simply no description, teaching or otherwise any suggestion in the cited documents for the problems of stabilizing fosfomycin tromethamol or how one would go about solving this problem. Therefore, regardless of whether one would have an understanding that salts would be more useful (as alleged by the Office), there is no description for the invention as claimed.

Once again, as discussed in the specification on page 1, fosfomycin tromethamol has instability problems caused by reactive functional groups and as such degrades. It should be recognized then that this instability leads to significant problems with storing the raw material, preparing compositions with the material, and storing the completed packages. In fact, as stated in the specification on page 1, line 12, the stability issues that have been

encountered with the Fosfomycin tromethamol means that as of the filing of the application, the pharmaceutical preparations that are available are in the form of hydrosoluble granules. The inventors discovery that certain substances (as defined in the specification and claims) stabilize fosfomycin tromethamol significantly advances the state of this field, permitting the possibility of actually using this material as an antibiotic.

The cited art does not address this issue at all. In fact, the Shastri patent simply describes that complexing a bioactive agent with a complexing agent increases the biological activity of the bioactive (see [0003] on page 1). Exemplary of the bioactive and the complexing agent are antibiotics (generally) and cyclodextrin (again see [0003]) and, in fact, only show data for cyclodextrin (see [0010]). There is nothing in Shastri to providing stability to anything, let alone fosfomycin. Shastri does describe fosomycin in a laundry list of antibiotics as one example among an all encompassing description useful as an active ([0022] on page 2). However, how is this in any way teaching how to stabilize fosfomycin tromethamol regardless of whether one would have wanted to use the salt form?

The secondary citation of the RxList Monographs simply provides information that the granular form is in a certain dosage form but alone or in combination with the Shastri patent does not provide even a hint at the stability problem with fosfomycin tromethamol or how one would even go about solving the problem. Therefore, it is respectfully submitted that the prior art cited in the rejection does not render the claimed invention obvious. Withdrawal of this rejection is requested.

A Notice of Allowance for pending claims 9-23 is also requested.

Respectfully submitted,

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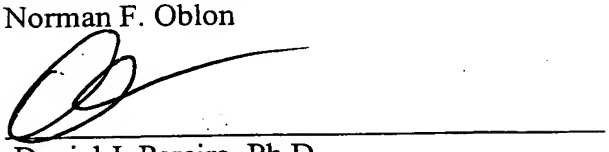

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